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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

J M SMITH CORPORATION d/b/a SMITH DRUG COMPANY, on behalf of itself and all others similarly situated,

Plaintiff,

v.

ABBVIE INC., ALLERGAN, INC., ALLERGAN SALES, LLC, ALLERGAN USA, INC., FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., FOREST LABORATORIES IRELAND, LTD., and FOREST LABORATORIES, LLC,

Defendants.

Case No. 20-cv-5735

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

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Plaintiff J M Smith Corporation d/b/a Smith Drug Company ("Plaintiff"), on behalf of itself and all others similarly situated, brings this Class Action Complaint against AbbVie, Inc. ("AbbVie"); Allergan, Inc., Allergan Sales, LLC, and Allergan USA, Inc. (collectively, "Allergan"); and Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Forest Laboratories, LLC, and Forest Laboratories Ireland Ltd. (collectively, "Forest") (together, AbbVie, Allergan and Forest are "Defendants") for Defendants' violations of the antitrust laws concerning the pharmaceutical drug Bystolic® (nebivolol hydrochloride) ("Bystolic"). Based on (a) personal knowledge, (b) the investigations of counsel, and (c) information and belief, Plaintiff alleges:

I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages arising out of the Defendants' unlawful exclusion of generic substitutes for the branded drug Bystolic, otherwise known as nebivolol hydrochloride or nebivolol HCl, a "beta blocker" used to treat high blood pressure. Forest and its successors manufacture the brand version of Bystolic, which is one of their key drugs, delivering nearly $1 billion in United States annual sales.[1] Although would-be generic manufacturers began applying with the United States Food and Drug Administration (the "FDA") to market generic nebivolol HCl on December 17, 2011,[2] no generic competitor has or will enter until September 17, 2021.

2. The only material difference between generic and brand name drugs is their price – generics are typically at least 50-80% less expensive when there are multiple generic competitors on the market. As a result, generics constitute both (a) an opportunity for drug purchasers to obtain enormous cost savings; and (b) a serious threat to the monopoly power and

[1] Glenmark Pharmaceuticals receives ANDA approval for Nebivolol Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg, https://www.glenmarkpharma.com/sites/default/files/Glenmark-receives-ANDA-approval-for-Nebivolol-Tablets%2C2.5-mg%2C5-mg%2C10-mg-and-20-mg.pdf, May 29, 2017.

[2] *See, e.g.*, 11/27/2015 Letter from Food and Drug Administration ("FDA") to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf.

profits of the manufacturer of the corresponding brand name drug. Indeed, AB-rated generics typically take 80% or more of the sales of a drug molecule from the brand name product within six months of generic entry. These extremely rapid erosion rates of the brand manufacturer's sales are due in large part to a unique feature of the pharmaceutical industry called drug substitution laws, which permit (and in many states require) dispensing pharmacies to substitute available AB-rated generic drugs for a brand drug unless the prescribing physician specifically orders otherwise.

3. Acutely aware of these realities, Forest engineered a series of unlawful reverse-payment deals (also known as "pay for delay" deals) with each of its would-be generic competitors, specifically, Hetero,[3] Torrent,[4] Alkem,[5] Indchemie,[6] Glenmark,[7] Amerigen[8] and Watson[9] (collectively, the "Generic Competitors"). From October 2012 through November 2013, Forest entered into these serial deals pursuant to which each generic (1) agreed not to compete with Forest or enter the market prior to September 17, 2021, unless another generic competitor entered the market earlier; and in exchange (2) received "side-deals," and cash payments, the precise amounts of which have not been publicly disclosed except that, on information and belief, they each exceed $15,000,000 in value. As corporate successors to one or more of the Defendants, Allergan and then AbbVie have continued this illegal collusion and unreasonable restraint of trade in the market for nebivolol HCl, all at the expense of purchasers. Every month of delayed generic competition has allowed Forest and its successors to unlawfully maintain many millions of dollars in monopoly profits from Bystolic without generic competition and

[3] Hetero USA, Inc. and Hetero Labs Ltd. (collectively, "Hetero").

[4] Torrent Pharmaceuticals Ltd., and Torrent Pharma, Inc. (collectively "Torrent").

[5] Alkem Laboratories Ltd. ("Alkem").

[6] Indchemie Health Specialties Private Ltd. ("Indchemie").

[7] Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals S.A. (collectively "Glenmark").

[8] Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. (collectively, "Amerigen").

[9] Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. ("Watson").

allowed the Generic Competitors to share in those profits by pocketing large and unjustified payments from Forest and its successors for agreeing to delay bringing generic nebivolol HCl to market.

4. Beginning on December 17, 2011,[10] after the Generic Competitors became the first generic manufacturers to seek approval from the FDA to market generic Bystolic, Forest sued each of them, accusing them of allegedly infringing U.S. Patent No. 6,545,040 (the "'040 Patent"), which Forest successfully submitted for listing in the FDA Orange Book by certifying that the patent covered Bystolic. These suits, filed in mid-March 2012, automatically triggered stays of FDA approval of the generic products (meaning that regardless of the merits of the patent infringement actions, the FDA could not grant final approval to any of the Generic Competitors to launch a generic product before June 18, 2015 absent an earlier favorable decision for the Generic Competitors or a dismissal of the actions). And foreclosing the Generic Competitors from launching also foreclosed all other generic manufacturers; as the first manufacturers to file for approval for generic Bystolic, the Generic Competitors were eligible to share 180 days of market exclusivity, free from competition from other generic manufacturers (other than a generic marketed or authorized to be marketed by Forest, also known as an "authorized generic"), once they actually launched their generic versions of Bystolic.

5. Between March 2012 through November 2013, while the stays were in effect, the Generic Competitors fought the patent infringement suits and prepared to bring their generic Bystolic to market to compete with Forest's branded Bystolic. At least six of the seven Generic Competitors would have been ready to launch well before September 17, 2021, as each had final FDA approval to do so as set forth in the table below:

[10] *See, e.g.*, 11/27/2015 Letter from FDA to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf; 5/27/2017 Letter from FDA to Glenmark, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf; 6/24/2015 Letter from FDA to Alkem, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203741Orig1s000ltr.pdf.

Manufacturer	ANDA No.	Final Approval Date
Amerigen	203659	4/16/15
Watson	203683	11/27/15
Alkem	203741	6/24/15
Glenmark	203821	5/25/17
Indchemie	203828	7/29/15
Torrent	203966	3/2/18

6. The Generic Competitors would have succeeded in the patent litigation because the '040 Patent was weak. The '040 Patent litigation likely would have concluded by mid-2015, including all appeals. The Generic Competitors would have won and launched by the later of: (a) June 2015, which was the expiry of the only other patent that Forest contended covered Bystolic, U.S. Patent No. 5,759,580 (the "'580 Patent"), or (b) the date their Abbreviated New Drug Applications ("ANDAs") were finally approved. But rather than risk facing competition from the Generic Competitors as early as June 2015 and the subsequent reduction in Bystolic brand sales and revenues such competition would cause, Forest paid the Generic Competitors to stay off of the market until September 21, 2021.

7. The side-deals that Forest provided to each Generic Competitor were intended to shield Forest from the risk of competition, and the Generic Competitors readily accepted these exclusionary side-deals to quit the patent fight.

8. On February 18, 2014 Actavis PLC and Forest announced an equity and cash merger.[11] On March 1, 2014 Forest's outside lawyers at Weil, Gotshal & Manges LLP were reviewing Forest's documents as part of their "work on the Actavis merger agreement."[12] On March 4, 2014, Forest's outside lawyers informed Forest in-house counsel Eric Agovino via email (the "Agovino email") that "[b]efore we engage in any discussions with the FTC . . . we

[11] *See* Actavis to Acquire Forest Laboratories, Inc. for ~$25 Billion in an Equity and Cash Transaction, https://www.businesswire.com/news/home/20140218005877/en/Actavis-Acquire-Forest-Laboratories-25-Billion-Equity.

[12] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-44 at 332).

think it would be prudent for us to review all of the Bystolic settlement and licensing agreements ***as well as the side agreements with those generic companies***."[13] Agovino replied:

> We entered into settlement agreements with the following defendants:
>
> 1) Hetero
>
> 2) Torrent
>
> 3) Alkem
>
> 4) Indchemie
>
> 5) Glenmark
>
> 6) Amerigen
>
> 7) Actavis [Watson's successor]
>
> ***All had side-deals*** (one was struck with Alkem, which is a related company with Indchemie).[14]

9. Forest's Agreement and Plan of Merger with Actavis PLC (the "Merger Agreement"), dated February 17, 2014 provides additional details. Specifically, in the Merger Agreement Forest disclosed its "material contracts," which are defined to include "any Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of $15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied."[15]

10. Forest listed each of the side-deals as a "material contract" "in connection with the settlement of BYSTOLIC patent dispute."

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[13] *Id*. (emphasis added).

[14] *Id*. (emphasis added).

[15] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

11. Thus Forest has described each of the side-deals set forth below as a "material contract," *i.e.*, it was a "Contract involving the settlement of any action or threatened action (or series of related actions) (A) which will (x) involve payments after the date hereof of consideration in excess of $15,000,000 or (y) impose monitoring or reporting obligations to any other Person outside the ordinary course of business or (B) with respect to which material conditions precedent to the settlement have not been satisfied." The respective contracts are set forth below.

12. **Hetero:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012 . . . together with the FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute."[16]

13. **Torrent:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012 . . . together with the PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[17]

14. **Alkem/Indchemie:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem Laboratories Ltd. dated November 27, 2012 . . . together with the TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute. AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT was executed on January 9, 2013" and "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Indchemie Health Specialties Private Ltd. dated November 27, 2012 . . . together with the TERM

[16] *Id*. at 179

[17] *Id*.

SHEET between Alkem Laboratories Ltd, Indchemie Health Specialties Private Ltd, and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute."[18]

15. **Glenmark:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012 . . . together with the COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[19]

16. **Amerigen:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013 . . . together with the BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute."[20]

17. **Watson:** "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013 . . . together with (a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between Actavis, Inc. and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute."[21]

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[18] *Id.*

[19] *Id.*

[20] *Id.* at 180.

[21] *Id.*

18. Forest listed the side-deals in the Merger Agreement because, on information and belief, they "involve payments after the date [t]hereof of consideration in excess of $15,000,000."

19. As Forest publicly acknowledged in the Agovino email, and in the Merger Agreement, the side-deals were entered into as part and parcel of Forest's patent settlement agreements with the Generic Competitors in the Bystolic patent litigation.

20. In addition to the consideration Forest provided each Generic Competitor in the form of a side-deal, Forest "agreed to reimburse certain of the Settling Defendants' legal costs in connection with the patent litigation."[22]

21. Forest also disclosed that its settlement agreements with the Generic Competitors "provide[d] a license to each of the Settling Defendants that will permit them to launch their respective generic versions of Bystolic as of the date that is the later of (a) three calendar months prior to the expiration of the '040 patent, including any extensions and/or pediatric exclusivities or (b) the date that each Settling Defendant receives final FDA approval of its ANDA, ***or earlier in certain circumstances***."[23] The bolded language typically refers to what is known as a "contingent launch provision" ("CLP"), or an "acceleration clause." CLPs ensure a settling generic that it will not be competitively disadvantaged should a later settling generic negotiate an earlier licensed entry date or otherwise come to market earlier: pursuant to the CLPs the entry date may be "accelerated" permitting the settling generic to enter the market at the same time as any of its competitors. CLPs ensure settling generic ANDA filers that, if any other ANDA filer somehow makes it to market before the agreed-upon licensed entry date, that ANDA filer's licensed entry date would be accelerated so that it could launch at the same time.

22. When CLPs are used, they generally operate the same way in each ANDA filer's settlement agreement. Under a CLP, the first-filing ANDA filer (or, as here, filers) obtains

[22] https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm.

[23] *Id*. (emphasis added).

protection from other first filers by agreeing to delay the launch of their generic products from the date of settlement until a date certain (here, exactly three months before the expiration of the '040 Patent),[24] but *if and only if* all other first-filer generic companies follow suit. By brokering the agreements, Forest ensured that, without regard to the strength of the Generic Competitors' challenges to the '040 Patent, Bystolic would have no generic competitors and Forest would maintain patent-generated monopoly profits until at least September 17, 2021, and none of its generic competitors would come to market earlier.

23. Reverse-payment agreements like the side-deals in this case delay the entry date for generic drug products beyond the date when competition would ensue in the absence of a reverse-payment. As the Third Circuit Court of Appeals put it, "when the parties' settlement includes a [payment], the generic also presumably agrees to an early entry date [before patent expiration] that is later than it would have otherwise accepted." *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015). Thus, without the ability to offer or accept an unlawful reverse-payment, Forest and the Generic Competitors would have instead agreed upon an earlier licensed entry date for generic versions of Bystolic. And, because of the CLPs, if *just one* of the Generic Competitors did not take an unlawful payment, and instead insisted on an earlier entry date untainted by a side-deal, *every other* Generic Competitor would enter on the same earlier date.

24. In sum, but for the anticompetitive reverse-payments, the Generic Competitors would have launched their generic products earlier either: (a) at risk; or (b) upon prevailing against Forest in the underlying patent litigation; or (c) via lawful settlement agreements providing for earlier negotiated entry dates untainted by the delay caused by the unlawful reverse-payments.

25. Had any of the above scenarios played out – as would have occurred absent the unlawful reverse-payments – Plaintiff and the Class it seeks to represent (defined below) would have paid substantially less for nebivolol HCl.

[24] *Id.*

26. Defendants' conduct was designed to, did, and continues to: (a) delay the entry of less expensive, AB-rated generic versions of Bystolic; (b) fix, raise, maintain or stabilize the price of nebivolol HCl; and (c) allocate 100% of the United States market for nebivolol HCl to themselves until three months before expiration of the '040 Patent.

27. Defendants' monopoly power in the nebivolol HCl market was maintained through willful exclusionary conduct, as distinguished from growth or development as a consequence of a legally-obtained valid patent, other legally-obtained market exclusivity, a superior product, business acumen, or historical accident.

28. As alleged below, Defendants' scheme violated Sections 1 and 2 of the Sherman Act, injuring Plaintiff and the Class of direct purchasers it seeks to represent (as defined below) and causing them to pay overcharges.

II. PARTIES

29. Plaintiff J M Smith Corporation, d/b/a Smith Drug Company is a corporation organized under the laws of the State of South Carolina and is located at 9098 Fairforest Road, Spartanburg, South Carolina 29301.

30. Defendant Forest Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 909 Third Avenue, New York, NY 10022. The negotiation, execution and enforcement of the unlawful reverse payments challenged herein all took place from Forest Laboratories, Inc.'s New York, NY principal place of business.

31. Defendant Forest Laboratories Ireland, Ltd. is an Irish Corporation with a place of business at Clonshaugh Industrial Estate, Dublin 17, Ireland.

32. Defendant Forest Laboratories Holdings, Ltd. is a Bermudian corporation having a principal place of business at 18 Parliament Street, Hamilton HM 11, Bermuda. In or around February 2006, Defendant Forest Laboratories Ireland, Ltd. changed its name to Forest

Laboratories Holdings, Ltd. and changed its residence from Ireland to Bermuda.[25]

33. Defendant Forest Laboratories, LLC is a company organized and existing under the laws of Delaware, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On July 1, 2014, in a series of transactions, Forest Laboratories, Inc. became a limited liability company named Forest Laboratories, LLC. On July 1, 2014, Actavis PLC ("Actavis") acquired Defendant Forest. On May 17, 2015 Actavis acquired Defendant Allergan, Inc. but maintained the name Allergan for its ongoing operations. Subsequently, on January 1, 2018, Forest Laboratories, LLC was merged with and into Defendant Allergan Sales, LLC, a Delaware limited liability company. As a result of these corporate consolidations, the Forest Defendants are predecessors in interest to Allergan Sales, LLC.

34. Defendant Allergan Sales, LLC is a company organized and existing under the laws of Delaware, with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

35. Defendant Allergan, Inc. is a Delaware corporation with its principal place of business located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

36. Defendant Allergan USA, Inc. is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

37. Allergan, through its merger with Forest, assumed responsibility for performance of the challenged provisions in the agreements, continued to perform those provisions, and benefited from making direct sales of Bystolic to Plaintiff and members of the proposed Class at the supracompetitive prices made possible by the delay those challenged provisions produced.[26]

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[25] *See, e.g.*, Notice and Stipulation of Name Change, *Forest Laboratories, et al. v. Ivax Pharmaceuticals, Inc., et al*, 03-cv-00891 (D. Del. Feb. 8, 2006) (ECF No. 536).

[26] *See, e.g.*, Bystolic label, available at https://www.dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=8b8ad213-1dc8-454e-a524-075685c0e1a8&type=display (listing Allergan USA Inc. as the distributor of Bystolic).

38. On information and belief, Forest assigned the reverse-payment agreements to Allergan, and Allergan never withdrew from them.

39. On information and belief, Allergan joined the ongoing unlawful course of conduct – and joined the unlawful reverse-payment agreements – with respect to the suppression of generic competition for Bystolic. Allergan did not withdraw from those conspiracies and instead continued to participate in them.

40. Defendant AbbVie, Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is the corporate successor to Allergan and Forest, having completed its purchase of Allergan on May 8, 2020.

41. Defendant AbbVie, through its merger with Allergan, assumed responsibility for performance of the challenged provisions in the agreements, continued to perform those provisions, and benefited from making direct sales of Bystolic to Plaintiff and members of the proposed Class at the supracompetitive prices made possible by the delay those challenged provisions produced.

42. On information and belief, Allergan assigned the reverse-payment agreements to AbbVie, and AbbVie never withdrew from them.

43. On information and belief, AbbVie joined the ongoing unlawful course of conduct – and joined the unlawful reverse-payment agreements – with respect to the suppression of generic competition for Bystolic. AbbVie did not withdraw from those conspiracies and instead continued to participate in them.

44. Although not named as a Defendant, Watson Pharma, Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Watson Pharma, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

45. Although not named as a Defendant, Watson Pharmaceuticals, Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Watson

Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Nevada, having places of business at 311 Bonnie Circle, Corona, CA 92880 and 360 Mount Kemble Avenue, Morristown, NJ 07962, and its corporate headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

46. Although not named as a Defendant, Torrent Pharmaceuticals Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Torrent Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Off. Ashram Road, Ahmedabad - 380 009, Gujarat, India.

47. Although not named as a Defendant, Torrent Pharma Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Torrent Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, MI 49009. On information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd. On information and belief, Torrent Pharma Inc. acts as the agent of Torrent Pharmaceuticals Ltd.

48. Although not named as a Defendant, Amerigen Pharmaceuticals Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Amerigen Pharmaceuticals Ltd. is a Chinese company having places of business at 197 State Route 18S, Suite 306N, East Brunswick, NJ 08816 and No. 58, Qunxing Yi Road, Suzhou Industrial Park, PRC. 215006.

49. Although not named as a Defendant, Amerigen Pharmaceuticals Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Amerigen Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 197 State Route 18S, Suite 306N, East Brunswick, NJ 08816. On information and belief, Amerigen Pharmaceuticals Inc. is a wholly-owned subsidiary of Amerigen Pharmaceuticals Ltd. On information and belief, Amerigen Pharmaceuticals Inc. acts as the agent of Amerigen Pharmaceuticals Ltd.

50. Although not named as a Defendant, Glenmark Generics Inc., USA was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Glenmark Generics Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, NJ 07430. Glenmark Generics Inc. is the same entity as Glenmark Generics Inc., USA. To the extent Glenmark Generics Inc. is an entity separate and apart from Glenmark Generics Inc., USA, any allegations in this Complaint relating to Glenmark Generics Inc., USA shall apply equally to Glenmark Generics Inc.

51. Although not named as a Defendant, Glenmark Generics Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Glenmark Generics Ltd. is an Indian company having a place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India.

52. Although not named as a Defendant, Defendant Glenmark Pharmaceuticals Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Glenmark Pharmaceuticals Ltd. is an Indian corporation having a principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India. On information and belief Glenmark Generics Inc., USA and Glenmark Generics Ltd. are wholly-owned subsidiaries of Glenmark Pharmaceuticals Ltd. On information and belief, Glenmark Generics Inc., USA is the North American division of Glenmark Generics Ltd. On information and belief, Glenmark Generics Inc., USA, Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd. have officers and directors in common. On information and belief, Glenmark Generics Inc., USA acts as the agent of Glenmark Generics Ltd. and Glenmark Pharmaceuticals Ltd.

53. Although not named as a Defendant, Hetero Labs Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Hetero Labs Ltd. is an Indian corporation having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estate,

Sanathnagar Hyderabad 500018 Andhra Pradesh, India.

54. Although not named as a Defendant, Hetero USA Inc. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1031 Centennial Avenue, Piscataway, NJ 08854. On information and belief, Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Ltd. On information and belief, Hetero USA Inc. acts as the agent of Hetero Labs Ltd.

55. Although not named as a Defendant, Indchemie Health Specialties Private Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Indchemie Health Specialties Private Ltd. is an Indian company having a place of business at 510, Shah & Nahar Industrila Estate, Dr. E. Moses Road, Worli-Mumbai 400018, India.

56. Although not named as a Defendant, Alkem Laboratories Ltd. was an initiator of and is a participant in the unlawful conspiracy described in this complaint. Alkem Laboratories Ltd. is an Indian company having a place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, Maharashtra, India.

57. All of the Defendants' and unnamed (as defendants) co-conspirators' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by the Defendants' and unnamed co-conspirators' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' and unnamed co-conspirators' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the Defendants and unnamed co-conspirators.

III. JURISDICTION AND VENUE

58. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff, and members of

the Class (defined below) resulting from Defendants' conspiracy and scheme to restrain trade in the United States market for nebivolol HCl. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, 15 U.S.C. § 15 and 15 U.S.C. § 22.

59. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a) and 22, and 28 U.S.C. §§ 1391(b), (c), and (d) because during the class period, Defendants resided, transacted business, were found, or had agents in the United States and in this District, and a substantial portion of the alleged conduct that affected interstate trade and commerce discussed herein has been carried out in the United States and in this District.

60. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

61. During the class period, Forest manufactured, sold and shipped Bystolic in a continuous and uninterrupted flow of interstate commerce. Defendants' anticompetitive conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

62. During the class period, each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their scheme.

63. This Court has personal jurisdiction over each Defendant, because each Defendant has – throughout the United States and including in this District – transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal scheme and conspiracy. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

64. This Court has personal jurisdiction over each Defendant under 15 U.S.C. § 22 because each transacts business in this District. This Court has specific personal jurisdiction under CPLR § 302(a) over all Defendants because Forest, from its then-principal place of business in New York, NY, did all of the following: (a) entered into the agreements containing

the challenged reverse payments to its co-conspirators; (b) made the promised reverse payments to its co-conspirators; (c) enforced its co-conspirators' delaying entry with generic Bystolic in consideration for those reverse payments; (d) sold branded Bystolic at supracompetitive prices made possible by the generic delay those reverse payments purchased; (e) earned as a result of those sales ill-gotten gains from the delay in generic Bystolic competition that those reverse payments purchased; and (f) assigned to its successors (the other named defendants) its obligations and benefits from the agreements containing the challenged reverse payments. Moreover, on information and belief, some or all of the agreements containing the challenged reverse payments direct application of New York law and select a New York forum. Personal jurisdiction also lies under Fed. R. Civ. P. 4(k)(2) over the foreign domiciliary defendants.

IV. CLASS ACTION ALLEGATIONS

65. Plaintiff brings this action on behalf of itself and, under Federal Rule of Civil Procedure 23(a) and (b)(3), as a representative of a class of direct purchasers (the "Class" or "Direct Purchaser Class") defined as follows:

> All persons or entities in the United States, including its territories, possessions, and the Commonwealth of Puerto Rico, who purchased brand Bystolic directly from any of the Defendants, or generic Bystolic directly from any drug manufacturer, at any time from June 2, 2015 until the effects of Defendants' conduct ceases (the "Class Period"). Excluded from the Class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal governmental entities.

66. Members of the Direct Purchaser Class are so numerous and/or geographically dispersed that joinder is impracticable. While the exact number of Class members is unknown to Plaintiff at this time, it is believed to be sufficiently numerous. The Class is readily identifiable from information and records in Defendants' possession.

67. Plaintiff's claims are typical of members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, Defendants'

anticompetitive conduct deprived the Class members of the benefits of competition from less-expensive generic versions of Bystolic, causing them to pay artificially inflated, supracompetitive prices for brand and generic Bystolic.

68. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

69. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and particularly class action antitrust litigation in the pharmaceutical industry.

70. Questions of law and fact common to members of the Class predominate over questions, if any, that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable questions are inherent in Defendants' wrongful conduct.

71. Questions of law and fact common to the Class include:

a. whether the conduct alleged herein constitutes a violation of the antitrust laws;

b. whether Defendants conspired with each of their Generic Competitors to suppress generic competition to Bystolic;

c. whether Defendants' challenged conduct suppressed generic competition to Bystolic;

d. Whether Defendants' challenged conduct fixed, raised, maintained or stabilized the price of nebivolol HCl;

e. whether a relevant antitrust market needs to be defined in this case in light of the existence of direct proof of Defendants' power to exclude generic competition and charge supracompetitive prices for Bystolic;

f. if a relevant antitrust market needs to be defined, what the definition of the relevant antitrust market for analyzing Defendants' monopoly power is, and whether Defendants had monopoly power in the relevant antitrust market;

g. whether Defendants illegally obtained or maintained monopoly power in the relevant market;

h. whether Defendants' actions were, on balance, unreasonable restraints of trade;

i. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

j. whether, and to what extent, Defendants' conduct caused antitrust injury (overcharges) to Plaintiff and the Direct Purchaser Class; and

k. the quantum of overcharge damages paid by the Class in the aggregate.

72. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that could not be practicably pursued individually, substantially outweigh potential difficulties in management of this class action.

73. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

V. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval and Substitution of Generic Drugs

74. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

75. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book within thirty days

of issuance any patents issued after the FDA approved the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

76. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

i. The Hatch-Waxman Amendments

77. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB" rating.

78. The FDCA and Hatch-Waxman Amendments operate on the proven scientific principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same relative extent and for the same amount of time as the brand counterpart. 21 U.S.C. § 355(j)(8)(B).

79. Congress enacted the Hatch-Waxman Amendments to expedite the entry of less-expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

80. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 86% of prescriptions.[27] Generics are now dispensed 95% of the time when a generic form is available.[28]

ii. ANDA Paragraph IV Certification

81. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

[27] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014), *available at* http://www.imshealth.com/cds/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf (last accessed June 6, 2014).

[28] *Id.* at 51.

21 U.S.C. § 355(j)(2)(A)(vii).

82. If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for alleged patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months from the date of receipt of the Paragraph IV notice, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (*i.e.*, grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the stay.

iii. First-Filer's 180 Day Exclusivity Period

83. Generics may be classified as (i) first-filer generics, (ii) later generic filers, and (iii) the brand's own authorized generic.

84. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification a 180 day period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand product are either invalid, unenforceable, or not infringed by the generic's product, the FDA cannot approve a later generic company's ANDA until that first-filing generic has been on the market for 180 days, or until the first-filer exclusivity has been extinguished or forfeited.

85. The Supreme Court has recognized that "this 180 day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first filer.[29]

86. A first-filer that informs FDA that it intends to wait until all Orange Book listed patents expire before marketing its product does not get a 180 day exclusivity period. Congress created this 180 day period to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

87. Where (as here) multiple generic companies are the first to file substantially complete ANDAs with Paragraph IV certifications, each is considered a "first applicant" and may be eligible to share the 180 day period.[30] If at least one first applicant remains eligible for the exclusivity, *i.e.*, the exclusivity has not been extinguished or forfeited, all subsequent ANDA filers must wait until the 180 day period expires before they can launch.

B. The Competitive Effects of AB-Rated Generic Competition

88. Since the FDA deems AB-rated generic versions of brand drugs to be just as safe and effective as their brand counterparts, the only material mode of differentiating the two is their price. On average, generics are at least 50% - 80% less expensive when there are multiple generic competitors on the market for a given brand.

89. Every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has affirmatively requested the brand). Accordingly, once one generic equivalent enters the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months.

90. By 12 months post-generic entry, the Federal Trade Commission ("FTC") found that on average, generics had captured 90% of corresponding brand drug sales and (with multiple

[29] *FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013).

[30] 21 U.S.C. § 355(j)(5)(B)(iv).

generics on the market) prices had dropped 85% relative to brand prices.[31] That is because, once multiple generic competitors enter, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other for market share by driving prices further down toward marginal manufacturing costs.[32] As a result, competition from generic drugs is viewed by brand drug companies, such as Forest, as a grave financial threat.

91. Generic competition enables purchasers (like Class members here) to purchase substantially cheaper generic versions of a drug instead of the more expensive brand, and to purchase generic versions of a drug at increasingly lower prices as generic prices fall over time and as more generic versions of that brand drug enter the market, causing generic prices to fall further.[33] In addition, generic competition enables purchasers to pay lower prices for their remaining brand purchases when the brand company lowers its brand price to compete with the generic for sales.

92. Conduct that delays generic entry harms direct purchasers (like Plaintiff and Class members here) in several ways. One way that direct purchasers are harmed (suffer overcharges) is that they are forced to continue purchasing the more expensive brand drug instead of the lower-priced generic equivalent they would have purchased had the generics entered earlier. In

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[31] *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010) ("FTC Pay-for-Delay Study"), http://www.ftc.gov/sites/default/files/documents/reports/ pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

[32] *See*, *e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311, 314, 339-41, 354-55 (Oct. 2000); Tracy Regan, *Generic Entry and Price Competition in the Prescription Drug Market--18 Years after the Waxman-Hatch Act* 24-25 (Univ. of Miami, Dep't of Econ., Working Paper, Feb. 14, 2004); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993, 1993-96 (Nov. 2007).

[33] *See, e.g.*, Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation* 19-20 (Nat'l Bureau of Econ. Research, Working Paper No. 16431, Oct. 2010); CONGRESSIONAL BUDGET OFFICE, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, at 32-33 (Jul. 1997); David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. OF ECON. AND STAT., 37, 43-44 (2005).

addition, conduct that delays generic entry causes direct purchasers to pay inflated generic prices because (a) generic prices fall over time, and so generic prices would have been lower if generic competition had started earlier and (b) brand prices typically increase over time[34] and the generic price is discounted off of the brand price,[35] and so the generic prices would have been lower if the generics had launched earlier, when the brand price was lower (since the generic price would have been discounted off a lower brand price).

93. Once exclusivity is lost and generic entry occurs – an event sometimes referred to as the "patent cliff" – the brand manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales. The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the Hatch-Waxman Act, and embraced by the states in their generic substitution laws. "According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Billions more are saved when hospitals use generics."[36]

[34] The price of brand Bystolic has increased substantially over the last five years. For example, Defendants increased the price of the 10 mg tablet of Bystolic repeatedly and significantly over the last five years, by 8.5% in October 2015, 9% in April 2016, 9% in January 2017, 9.5% in January 2018, 9.5% in January 2019, and 5% in January 2020 – in total increasing the price of the 10 mg tablet of Bystolic by 62% over the last five years. Defendants took nearly identical price increases on the other strengths of Bystolic, increasing the prices of the various strengths of Bystolic by 60-62% over the period from June 2015 through today.

[35] In order to be automatically substituted for the corresponding brand, generic products must be less expensive than the corresponding brand. *E.g.*, Cal. Bus. & Prof. Code § 4073(c); Tx. Admin. Code § 309.3(a)(1); Fla. Stat. § 465.025(2); 35 Pa. Code § 960.3(a); N.Y. Educ. Law § 6816-a. Generic prices are set as a percentage discount off the brand price. *See, e.g.*, *In re Namenda Antitrust Litig.*, 1:15-cv-07488-CM-RWL (S.D.N.Y. Mar. 5, 2019), (ECF No. 668-4) (assumption listed in cell A43 of a pharmaceutical manufacturer sales forecast is that the generic will initially be priced at a 40 percent discount off the brand price and then will drop to a 90% discount from the brand price).

[36] *Generic Drugs Undergo Rigorous FDA Scrutiny*, U.S. Food & Drug Admin. (Oct. 8, 2014), https://www.fda.gov/consumers/consumer-updates/generic-drugs-undergo-rigorous-fda-scrutiny.

C. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

94. Because the Hatch-Waxman regulatory scheme automatically delays approval of an ANDA whenever a brand name manufacturer sues the potential generic competitor for alleged patent infringement, brand name manufacturers frequently take aggressive positions in listing patents in the Orange Book, and then bring patent lawsuits against any generic competitor that files an ANDA with a Paragraph IV certification. Brand name manufacturers often sue generics simply to delay generic competition, rather than to enforce valid patents against infringing products.

95. In connection with the resolution of patent litigation arising out of Paragraph IV Certifications, some brand name manufacturers have entered into "settlements" in which the brand name manufacturer pays off its generic competitors in exchange for a delay in generic competition. These exclusion payment agreements among horizontal competitors not to compete are commonly known as "pay-for-delay" or "reverse-payment agreements." Brand and generic manufacturers execute exclusion payment agreements as purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers. The brand name manufacturer preserves increased profits by keeping its monopoly intact via a payment of some of the monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product.

96. Initially reverse-payment agreements took the form of a straight cash payment from the brand name manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and class action lawsuits, brand name manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements. For example, the reverse-payment deals that were the subject of *FTC v. Actavis*, *Inc.*, 570 U.S. 136 (2013) involved payments allegedly hidden in co-promotion and manufacturing side-deals entered into in connection with settlement of patent litigation over the brand drug AndroGel. Because the profits to be gained by

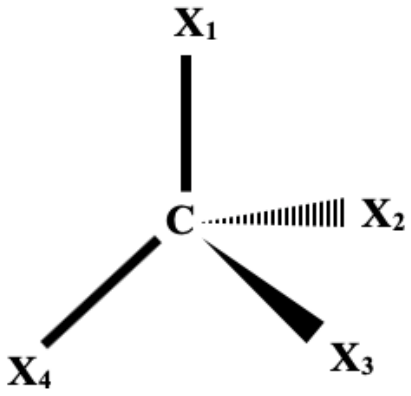
delaying generic competition are so great, however, drug manufacturers retain the incentive to enter into such agreements.

VI. FACTUAL ALLEGATIONS

A. Basic Chemistry Relating to the Active Pharmaceutical Ingredient in the Drug Product Bystolic

97. Molecules are composed of atoms (*e.g.*, carbon, nitrogen or hydrogen) that are bonded to each other through the sharing of electrons. The atom carbon forms four bonds and tends to adopt a tetrahedral structure. That three-dimensional arrangement can be envisioned as a tetrahedron with the carbon atom at the center and the four substituents at the four vertices of the tetrahedron.

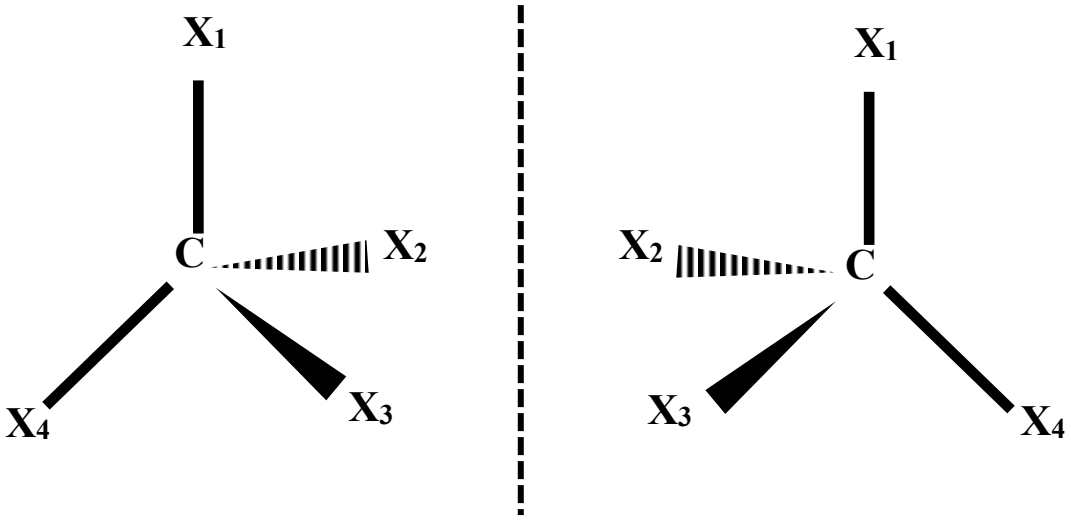
98. The chemical symbol for a carbon atom is "C." The figure below depicts a carbon atom (labeled as "C") bonded to four different chemical substituents (labeled as "X_1," "X_2," "X_3," and "X_4"). The straight lines from the carbon atom (at the center) to "X_1" and "X_4" are



intended to convey that they are in the plane of the page. The solid wedge from the carbon atom to "X_3" is intended to convey that it is coming out of the page towards the reader. And the hashed wedge from the carbon atom to "X_2" is intended to convey that it is coming out of the page but away from the reader. Thus, the above figure reflects a three-dimensional tetrahedral structure with a carbon atom at its center.

99. When a carbon atom is attached to four different substituents in a tetrahedral arrangement such as that shown above, the substituents can be arranged in either of two

conformations, as depicted below, with a mirror line between them. Note that, much like one's



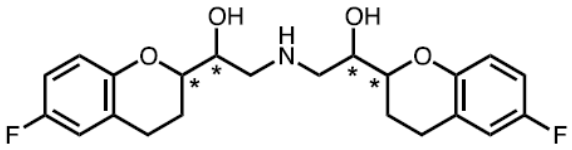
left and right hands, these two arrangements are mirror images of one another. And, much like one's left and right hands, they cannot be superimposed on one another by rotation. A carbon atom bonded to four different substituents can thus exist as either of two "stereoisomers" and such a carbon atom is referred to as a "chiral center." Naming conventions exist to distinguish these two stereoisomers from one another, and a commonly used terminology refers to one configuration as the "R" configuration and the other as the "S" configuration.

100. Distinguishing between stereoisomers can be particularly important in biological systems because many active pharmaceutical ingredients ("APIs") in drugs interact with naturally occurring receptors in the human body by fitting into a three-dimensional site on the receptor, much like a left hand fits into a left-handed glove. Just as a left hand would not fit properly into a right-handed glove, the wrong stereoisomer often will not fit into the intended receptor site. Thus, it is not uncommon for one stereoisomer to exhibit a desired pharmacological activity in biological systems while the other does not.

101. Carbon is so ubiquitous in organic chemicals that a carbon atom in chemical structures is often abbreviated as a vertex, rather than as a "C," with the understanding that such vertices are carbon. The chemical symbol for hydrogen is "H" and hydrogen only forms one bond. Because hydrogen is also ubiquitous and the number of chemical bonds that carbon and hydrogen make (*i.e.*, 4 and 1, respectively) is so well known, hydrogen is often omitted from

chemical structures and its presence is assumed when a carbon has less than four bonded substituents.

102. On March 31, 1987, the United States Patent and Trademark Office ("PTO") issued United States Patent No. 4,654,362 ("the '362 Patent"). The '362 Patent disclosed a number of different chemical compounds, including the following chemical compound:



103. The unlabeled vertices above correspond to a carbon atom and each of those carbon atoms (vertices) is connected to other atoms. To the extent a particular carbon atom has less than four bonds depicted, the remainder are hydrogen atoms. With this understanding in mind, each asterisk in the above chemical structure corresponds to a chiral center – *i.e.*, a carbon atom bonded to four different substituents – that can adopt either of two configurations that can be labeled as either an "R" or "S" configuration. As a result, the above chemical structure discloses ten different possible stereoisomers with the following configurations:

1. SRRR
2. RSSS
3. SRRS
4. RSSR
5. SRSR
6. SRSS
7. RSRR
8. RRSS
9. SSSS
10. RRRR

104. Forest was, and its successor in interest Allergan is, the holder of NDA No. 21-742 for Bystolic. The active ingredient in Bystolic is a mixture of two of the above ten stereoisomers: the SRRR and RSSS stereoisomers (*i.e.*, nos. 1 and 2, above). The mixture of

these two stereoisomers is referred to as nebivolol, and both are present in Bystolic as a hydrochloride salt.

B. Forest's Bystolic Patents

105. Forest certified to FDA that the '040 and '580 Patents covered Bystolic, and FDA listed those patents in the Orange Book. The '580 Patent issued on June 2, 1998 and expired seventeen years later, on June 2, 2015. Accordingly, the '580 Patent afforded Forest no protection from generic competition for Bystolic beyond June 2, 2015.

106. The '040 Patent issued from United States Application Serial No. 07/825,488 ("the '488 Application") filed on January 24, 1992. To understand the impact of prosecution of the '488 Application at the PTO on the scope of the issued claims in the '040 Patent, it is important to understand the effect of the choice of transition in a patent claim. "A patent claim typically has three parts: the preamble, the transition, and the body." Donald S. Chisum, CHISUM ON PATENTS § 8.06[1](b) (2003). "The preamble is an introductory phrase that may summarize the invention, its relation to the prior art, or its intended use or properties." *Id.* § 8.06[1](b)[i]. "The transition is a phrase connecting the preamble to the body of the claim. The content of the phrase may indicate whether the elements stated in the body are 'open' or 'closed.'" *Id.* § 8.06[1](b)[ii]. "The body of the claim is the recitation or listing of the elements and limitations which define the product or process to be encompassed within the patent monopoly." *Id.* § 8.06[1](b)[iii].

107. There are three commonly used transitional phrases: "comprising," "consisting of," and "consisting essentially of." *Id.* § 8.06[1](b)[ii]; *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006). These are "terms of art in patent law that 'define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.'" *Id.* (quoting the Manual of Patent Examining Procedures). At one end of the spectrum, the phrase "comprising" signifies that the claim is "open" to the addition of unrecited components or steps. *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). For example, a claim reciting a product "comprising"

three ingredients A, B and C encompasses a product composed of A, B, C and D (*i.e.*, the addition of D to the A-B-C combination does not avoid infringement).

108. The originally-filed claims in the application that issued as the '040 Patent employed the open transition "comprising." For example, originally-filed claim 19 covered pharmaceutical compositions "comprising" a "pharmaceutically acceptable carrier" and the SRRR and RSSS stereoisomers of nebivolol. The use of the open transition "comprising" meant that original claim 19 covered formulations having the SRRR and RSSS stereoisomers of nebivolol, even if the formulations also included some or all of the other eight unclaimed stereoisomers of nebivolol. The PTO examiner therefore rejected those claims based upon the prior art '362 Patent described above. The examiner reasoned that the '362 Patent taught mixtures of various of the stereoisomers described above, and thus were covered by pending claim 19.

109. In response, the applicants admitted that the '362 Patent taught "undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of the Base Compound. . . ." More specifically, the applicants admitted that "Compound 84 . . . is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 . . . is an undefined mixture of the RSRS, RSSR, and SRRS isomers." In an attempt to overcome the rejection, the applicants narrowed the claims by substituting new claims utilizing the transition "consisting essentially of" rather than "comprising." In doing so, the applicants emphasized that the purpose of the amendment was to distinguish their claims from the undefined mixtures of other nebivolol isomers disclosed in the Prior Art '362 Patent:

> Claims 18 and 19 have been rewritten as new Claims 25 and 26. Claim 25 recites "A composition consisting essentially of the compound . . .", and Claim 26 recites "A pharmaceutical composition consisting essentially of . . . [the two compounds (a) and (b)]". This amendment is being made to more clearly distinguish the claimed invention over the prior art ['362 Patent] which, as is explained in detail below, discloses undefined mixtures that may include the presently claimed compounds in admixture with other stereoisomers of [nebivolol]. Favorable consideration of the amended claims is respectfully requested.

110. The transition "consisting essentially of" in a patent claim narrows the claim relative to "comprising." *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). "[W]ith respect to a 'consisting essentially of' claim, there is no infringement where the accused product contains additional, unclaimed ingredients that materially affect the basic and novel properties of the invention." *Yoon Ja Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1320-21 (Fed. Cir. 2006). Thus, for a claim reciting a product "consisting essentially of" ingredients A, B and C, the addition of unrecited ingredient D will avoid infringement if D has a material effect on the basic and novel properties of the claimed invention.

111. The PTO examiner, however, was not persuaded that the use of the "consisting essentially of" transition distinguished the then-pending claims from the '362 Patent. He therefore maintained his rejection of the claims. The applicants for the '040 Patent again argued that it was impossible to tell from the '362 Patent which stereoisomers, and in what amounts, were definitely present in the disclosed mixtures:

> There is no way that one can determine from the teachings of the patent the specific stereoisomeric configuration of [the prior art '362 Patent's] compound Nos. 84 and 87.

The Examiner continued to maintain his rejections and ultimately issued a final rejection of the "consisting essentially of" Claims 25 and 26, as anticipated by the '362 Patent. He also rejected the claims as obvious.

112. The applicants for the '040 Patent appealed the examiner's final anticipation and obviousness rejections to the Board of Patent Appeals and Interferences ("the Board"). In their brief, the applicants continued to argue that it was impossible to say exactly which stereoisomers (and how much of them) were present in Compound 84 of the prior art '362 Patent, but that the "possible" stereoisomers present in unknown amounts were RSRR, RSSS, SRRR and SRSS. During the course of briefing the appeal to the Board, the Examiner dropped the anticipation rejection.

113. The Board nevertheless addressed the anticipation issue and made certain findings and conclusions regarding the relationship between then-pending Claim 26 and Compound 84 of the '362 Patent. Specifically, the Board concluded:

> [The '362 Patent's] disclosure of compound 84, together with its designation "AB," appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers "just as surely as if they were identified in the reference by name."

114. The Board then determined that the "consisting essentially of" transition in then-pending Claim 26 caused the claim to cover the undefined mixture of isomers in the Prior Art '362 Patent:

> It is well settled that "the phrase 'consisting essentially of' limits the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristic(s) of a composition." Here, a basic and novel characteristic of the pharmaceutical composition of claim 26 is its blood pressure reducing or antihypertensive effect. Thus, claim 26 is open to ingredients that do not materially affect its antihypertensive activity. [The prior art '362 Patent's] antihypertensive compound 84 is a mixture of four stereoisomers: RSSS, SRRR, RSRR and SRSS. ***Because the RSSR and SRSS stereoisomers do not materially affect blood pressure reducing or antihypertensive activity, it appears that they are not excluded from the composition of claim 26***.

(internal citation omitted and emphasis added). Accordingly, the Board ordered the Examiner to reconsider his withdrawal of the anticipation rejection based on the Prior Art '362 Patent:

> Specifically, the examiner should consider whether claim 26 'reads on' [the '362 Patent's] compound 84 taking into account the appropriate principles of claim interpretation and the foregoing remarks.

The very clear upshot of the Board's decision was that the claims of the '488 Application were not patentable unless the claims excluded the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers.

115. On remand from the Board, the applicants for the '040 Patent did not even attempt to argue against anticipation in view of the Board's opinion. Instead, they further narrowed their claims by replacing "consisting essentially of" with "consisting of," in new Claims 27 and 28. And based on that change, applicants argued that the new "consisting of" limitation excluded the undefined mixture of possible stereoisomers in the '362 Patent:

> Applicants respectfully submit that the claims, as amended, are patentable over [the prior art '362 Patent]. Applicants submit that neither a composition consisting of the RSSS enantiomer, nor a composition consisting of the RSSS enantiomer and its enantiomer the SRRR enantiomer, are disclosed in [the '362 Patent]. [The '362 Patent] discloses the base compound, as an undefined mixture of stereoisomers, as compound 84 (designated as "AB") and 87 (designated as "AA"), shown in the table in Col. 21 of the patent.

116. Once again, the applicants expressly noted that "Compound 84 [of the prior art '362 Patent] is an undefined mixture of the RSRR, RSSS, SRSS and SRRR isomers, and Compound 87 [] is an undefined mixture of the RSRS, RSSR, and SRRS isomers." They argued that the new "consisting of" language excluded compounds containing such additional isomers:

> [I]t is clear that the cited [the '362 Patent] discloses neither a composition consisting of the RSSS enantiomer of the base compound, nor a composition consisting of the RSSS and SRRR enantiomers.

117. And again, applicants did not distinguish their claims based on any particular amount or source of possible unrecited stereoisomers in the "undefined mixture" of the '362 Patent.

118. The phrase "consisting of" is the narrowest of the transitions and it "signifies restriction and exclusion of unrecited steps or components." Manual of Patent Examining Procedures § 2111.03; *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004). In light of the Board's reasoning and the applicants' comments and amendments, it is clear that the narrowing amendment was intended to and did exclude the presence of the unclaimed stereoisomers, particularly the RSSR and SRSS stereoisomers (*i.e.*, the claims do not cover formulations containing the unclaimed stereoisomers, especially the RSSR and SRSS stereoisomers).

119. The Examiner then allowed the "consisting of" Claims 27 and 28, which ultimately issued as Claims 2 and 3 of the '040 Patent in 2003.

120. Subsequently, the '040 Patent was subjected to reexamination proceedings and a reexamination certificate issued in 2009.

C. The Generic Competitors File ANDAs for Generic Versions of Bystolic

121. Alkem, Amerigen, Glenmark, Indchemie, Hetero, Torrent and Watson were the first generic manufacturers to file ANDAs with the FDA containing Paragraph IV certifications regarding Bystolic patents. For example, in letters granting final approval to their ANDAs, the FDA noted that each was "one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Nebivolol Tablets."[37]

122. Because the Generic Competitors were the first companies to file substantially complete ANDAs with Paragraph IV certifications, they each stood to receive 180 days of marketing exclusivity during which the FDA would not give final approval to any later ANDA filer's generic equivalent of Bystolic.

123. Forest received the Generic Competitors' Paragraph IV notice letters on the following dates:

- Torrent: February 2, 2012[38]
- Indchemie: February 3, 2012[39]
- Alkem: February 3, 2012[40]
- Watson: February 13, 2012[41]
- Amerigen: February 16, 2012[42]
- Glenmark: February 20, 2012[43]

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[37] *See, e.g.*, 11/27/2015 Letter from FDA to Watson, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/203683Orig1s000Ltr.pdf; 5/27/2017 Letter from FDA to Glenmark, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/203821Orig1s000ltr.pdf; 6/24/2015 Letter from FDA to Alkem, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/ 203741Orig1s000ltr.pdf.

[38] *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 93).

[39] *Forest Laboratories, et al. v. Indchemie Health Specialties PVT et al.*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1 ¶ 22).

[40] *Id.* ¶ 38.

[41] *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1 ¶ 108).

[42] *Id.* ¶ 123.

- Hetero: February 17, 2012[44]

124. Because they contained Paragraph IV certifications, these notice letters were required to include a detailed statement of the factual and legal bases as to why the '040 Patent was invalid, unenforceable, and/or not infringed by their ANDA products. The Paragraph IV notice letters were required to include an offer of confidential access to each Generic Competitor's ANDA under the Hatch-Waxman Act. The notice letters gave rise to a potential cause of action for patent infringement, thereby allowing Forest to file suit against the Generic Competitors under the Hatch-Waxman Act (if Forest otherwise had a basis to sue under Rule 11).

D. The Bystolic Patent Litigation

125. On March 13, 2012, in response to their Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Torrent, Watson, Amerigen, Glenmark, and Hetero.[45]

126. On March 14, 2012, in response to their Paragraph IV certification letters, Forest filed a patent infringement lawsuit in the United States District Court for the Northern District of Illinois against Indchemie and Alkem.[46]

127. By order of the Judicial Panel for Multidistrict Litigation, these cases were consolidated into *In re Nebivolol Patent ('040) Litigation*, 12-cv-5026 (N.D. Ill. June 12, 2012) (ECF No. 1) (hereafter referred to as the "Nebivolol Patent Litigation").

128. Forest could not prevail in the Nebivolol Patent Litigation. The sole independent claim asserted by Forest in the Bystolic Patent Litigation was claim 2, as shown below:

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[43] *Id.* ¶ 138.

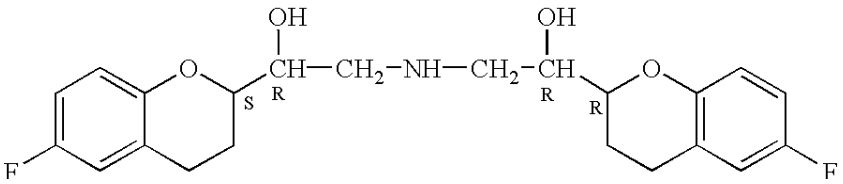
[44] *Id.* ¶ 153.

[45] *Forest Laboratories, et al., v. Torrent Pharmaceuticals Ltd. et al.*, 12-cv-05030 (D. Del. Mar. 13, 2012) (ECF No. 1).

[46] *Forest Laboratories, et al. v. Indchemie Health Specialties PVT et al.*, 12-cv-01855 (N.D. Ill. Mar. 14, 2012) (ECF No. 1).

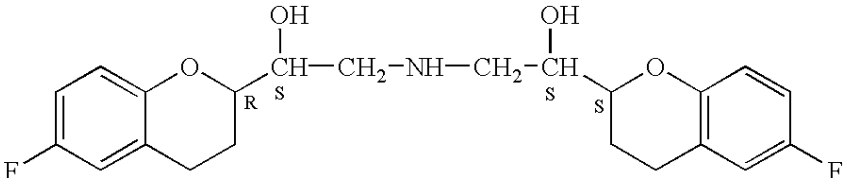
2. A pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients:

(a) the blood pressure reducing compound [2S,αR, 2′R,α′R]-α,α′-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:



or a pharmaceutically acceptable acid addition salt thereof; and

(b) the compound [2R,αS,2′S,α′S]-α,α′-[iminobismethylene]bis[6-fluoro-3,4-dihydro-2H-1-benzopyran-2-methanol] having the formula:



or a pharmaceutically acceptable acid addition salt thereof.

’040 Patent at 11:33-12:22. Thus, claim 2 is limited to a pharmaceutical composition consisting of a pharmaceutically acceptable carrier and, as active ingredients, SRRR-nebivolol and RSSS-nebivolol (or pharmaceutically acceptable acid addition salts).

129. The Generic Competitors were well aware of the prosecution history of the ’040 Patent and the narrowing amendments the applicants had made. During claim construction proceedings in the Nebivolol Patent Litigation, they correctly argued that the term “consisting of” in claim 2 of the ’040 Patent “excludes any unrecited stereoisomers of nebivolol.” The Generic Competitors’ products did not infringe because they included at least small amounts of the unrecited stereoisomers of nebivolol, including the RSSR and SRSS stereoisomers.

130. Early on in the Bystolic Patent Litigation, the Generic Competitors pressed the argument that the “consisting of” transition precluded the use of a plurality of inactive ingredients. Their position was premised on the argument that (1) a “pharmaceutically acceptable

carrier" referred to an individual inactive ingredient in a pharmaceutical formulation; (2) the "consisting of" transition "closed" the claim to unrecited inactive ingredients; and (3) therefore, the claims did not cover formulations having two or more inactive ingredients. At least one other court has construed "pharmaceutically acceptable carrier" to mean "a conventional pharmaceutically acceptable excipient or additive. . . ." *Schering Corp. v. Mylan Pharms., Inc.*, 2011 U.S. Dist. LEXIS 63825, at *36 (D.N.J. Jun. 15, 2011). To the extent this interpretation applied in the Nebivolol Patent Litigation, the Generics' products did not infringe for this additional reason.

131. As a result of the foregoing, Forest could not prevail in proving literal infringement of the asserted claims of the '040 Patent. And, in light of the prosecution history of the '040 Patent, Forest could not prevail based on the doctrine of equivalents. In addition, Forest's invalidity defenses concerning the asserted claims of the '040 Patent were weak and it could not have prevailed against the Generics' invalidity arguments. As the Board explained during the prosecution of the '040 Patent:

> [The '362 Patent's] disclosure of compound 84, together with its designation "AB," appears to describe the individual RSSS, SRRR, RSRR and SRSS stereoisomers "just as surely as if they were identified in the reference by name."

The '362 Patent was prior art to the '040 Patent. In light of the '362 Patent's essentially explicit teaching of a mixture of "the individual RSSS, SRRR, RSRR and SRSS stereoisomers" of nebivolol, the asserted compositions in the '040 Patent were anticipated by, or obvious in view of, the prior art, including other pertinent prior art such as Van de Water et al., Pharmacological and Hemodynamic Profile of Nebivolol, a Chemically Novel, Potent, and Selective B1-Adrenergic Antagonist, Journal of Cardiovascular Pharmacology, 11, No. 5, 552-563 (1988). Any purported evidence of secondary indicia of nonobviousness was insufficient to overcome the clear prima facie obviousness of the claims.

E. Forest Enters into Unlawful Reverse-Payment Agreements with the Generic Competitors

132. Starting on October 24, 2012, Forest began entering into settlements with Generic Competitors to resolve the Nebivolol Patent Litigation. Forest's internal and external counsel have conceded that each of these settlements also included "side-deals":

To: 'Malester, Ann'[]; Newborn, Steven[steven.newborn@weil.com]
From: Agovino, Eric
Sent: Tue 3/4/2014 7:47:28 PM
Importance: Normal
Subject: RE: Namenda settlements
Received: Tue 3/4/2014 7:47:00 PM
EXECUTED Forest-Hetero Settlement and License Agreement.pdf
EXECUTED Term Sheet (Hetero).pdf

We entered into settlement agreements with the following defendants:

1) Hetero

2) Torrent

3) Alkem

4) Indchemie

5) Glenmark

6) Amerigen

7) Actavis

All had side deals (one side was struck with Alkem, which is a related company with Indchemie).

Attached are the Hetero agreements.

From: Malester, Ann [mailto:Ann.Malester@weil.com]
Sent: Tuesday, March 04, 2014 9:15 AM
To: Agovino, Eric; Newborn, Steven
Subject: RE: Namenda settlements

Eric,

Before we engage in any discussions with the FTC on the Namenda agreements, we think it would be prudent for us to review all of the Bystolic settlement and licensing agreements as well as the side agreements with those generic companies. Could you put together the same type of information for Bystolic as you sent us for Namenda?

Thanks so much, Ann

133. These side-deals were also listed in Forest's Merger Agreement with Actavis, as "material contracts" that on information and belief "involve payments . . . of consideration in excess of $15,000,000."[47] In addition, Forest has also admitted that it reimbursed "certain of the

[47] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 69).

Settling Defendants' legal costs in connection with the patent litigation."[48] Accordingly, on information and belief, Forest paid each Generic Competitor at least $15,000,000 but likely more, in reverse-payments to resolve the Nebivolol Patent Litigation and induce the Generic Competitors to quit the patent fight.

134. The **Hetero** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Hetero USA Inc. and Hetero Labs Ltd. dated October 24, 2012," plus payment for Hetero's expended litigation costs, and a "FINAL TERM SHEET between Hetero Drugs Ltd. and Forest Laboratories Ireland Ltd. dated October 5, 2012, in connection with the settlement of BYSTOLIC patent dispute."[49]

135. On information and belief, in addition to the monies Forest paid Hetero for Hetero's expended litigation costs, pursuant to the "FINAL TERM SHEET," Forest paid Hetero more than $15,000,000.

136. The **Torrent** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. dated November 21, 2012," plus payment for Torrent's expended litigation costs, and a "PATENT ASSIGNMENT AGREEMENT between Torrent Pharmaceuticals Ltd and Forest Laboratories Holdings Ltd. dated November 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[50]

137. On information and belief, in addition to the monies Forest paid Torrent for Torrent's expended litigation costs, pursuant to the "PATENT ASSIGNMENT AGREEMENT," Forest paid Torrent more than $15,000,000.

138. The **Alkem** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Alkem

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[48] https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm.

[49] *In re Namenda Direct Purchaser Antitrust Litig.*, 15-cv-07488-CM-RWL (S.D.N.Y. Mar. 7, 2019) (ECF No. 680-22 at 179).

[50] *Id.*

Laboratories Ltd. dated November 27, 2012," plus payment for Alkem's expended litigation costs, and a "TERM SHEET between Alkem Laboratories Ltd., Indchemie Health Specialties Private Ltd., and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute." Alkem and Forest also entered into an "AMENDMENT NO. 1 TO SETTLEMENT AGREEMENT . . . on January 9, 2013."[51]

139. On information and belief, in addition to the monies Forest paid Alkem for Alkem's expended litigation costs, pursuant to the Alkem "TERM SHEET," Forest paid Alkem more than $15,000,000.

140. The **Indchemie** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Indchemie Health Specialties Private Ltd. dated November 27, 2012," plus payment for Indchemie's expended litigation costs, and a "TERM SHEET between Alkem Laboratories Ltd, Indchemie Health Specialties Private Ltd, and Forest Laboratories Ireland Ltd. dated November 28, 2012, in connection with the settlement of BYSTOLIC patent dispute."[52]

141. On information and belief, in addition to the monies Forest paid Indchemie for Indchemie's expended litigation costs, pursuant to the Indchemie "TERM SHEET," Forest paid Indchemie more than $15,000,000.

142. The **Glenmark** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd, and Glenmark Generics Inc., USA and Glenmark Generics Ltd. dated December 21, 2012," plus payment for Glenmark's expended litigation costs, and a "COLLABORATION AND OPTION AGREEMENT between Glenmark Pharmaceuticals S.A. and Forest Laboratories Holdings Ltd. dated December 21, 2012, in connection with the settlement of BYSTOLIC patent dispute."[53]

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[51] *Id.*

[52] *Id.*

[53] *Id.*

143. On information and belief, in addition to the monies Forest paid Glenmark for Glenmark's expended litigation costs, pursuant to the "COLLABORATION AND OPTION AGREEMENT," Forest paid Glenmark more than $15,000,000.

144. The **Amerigen** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013," plus payment for Amerigen's expended litigation costs, and a "BINDING TERM SHEET COLLABORATION AGREEMENT between Forest Laboratories, Inc. and Amerigen Pharmaceuticals, Ltd. dated July 18, 2013, in connection with the settlement of BYSTOLIC patent dispute."[54]

145. On information and belief, in addition to the monies Forest paid Amerigen for Amerigen's expended litigation costs, pursuant to the "BINDING TERM SHEET COLLABORATION AGREEMENT," Forest paid Amerigen more than $15,000,000.

146. The **Watson** reverse-payment included the "SETTLEMENT AGREEMENT between Forest Laboratories, Inc. and Forest Laboratories Holdings, Ltd., and Watson Laboratories, Inc. (NV), Watson Laboratories, Inc. (DE), Watson Laboratories, Inc. (NY), Watson Laboratories, Inc. (CT), Watson Pharma, Inc., and Actavis, Inc. dated November 6, 2013," plus payment for **Watson** expended litigation costs, and "(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE AGREEMENT between [Watson] and Moksha8, Inc. dated November 4, 2013, in connection with the settlement of BYSTOLIC patent dispute."[55]

147. On information and belief, in addition to the monies Forest paid Watson for Watson's expended litigation costs, pursuant to the "(a) the LETTER from Forest Laboratories, Inc. to Moksha8, Inc. dated November 1, 2013 and (b) TERMINATION AND RELEASE

[54] *Id*. at 180.

[55] *Id*.

AGREEMENT between [Watson] and Moksha8, Inc.," Forest paid Watson more than $15,000,000.

148. On information and belief, the value of each reverse-payment exceeded Forest's avoided litigation costs.

149. In exchange for these reverse-payments, each Generic Competitor agreed not to compete with Forest in the market for nebivolol HCl, in which Forest had a monopoly, for so long as all others did so also, until September 17, 2021 (a mere three months prior to expiry of the '040 Patent).[56]

150. The purpose and effect of the reverse-payment agreements were to delay Forest from having to face lower-priced generic competition for years.

151. But for the reverse-payment agreements, the Generic Competitors would have been ready, able, and willing to launch their generic versions of Bystolic much earlier.

152. Specifically, the Generic Competitors would have launched by the later of: (a) June 2015, which was the expiry of the only other patent that Forest contended covered Bystolic (the '580 Patent), or (b) the date their ANDAs were finally approved.[57]

153. By operation of the CLPs, if *just one* Generic Competitor launched a generic version of Bystolic prior to September 17, 2021 pursuant to any of the three above scenarios, *all* of the other Generic Competitors would have entered the market.

154. By about October 2012, when Forest and the Generic Competitors began entering into the reverse-payment agreements, Bystolic was generating hundreds of millions of dollars per year in revenues for Forest. Losing a substantial portion of that revenue stream in the event any of the Generic Competitors were to prevail on non-infringement or other defenses – or in the event that Forest had not induced the Generic Competitors with reverse-payments to agree to delay launching generic Bystolic – would have drastically reduced Forest's profits. Thus, Forest

[56] https://www.sec.gov/Archives/edgar/containers/fix010/38074/000003807413000024/R17.htm.

[57] *See* ¶ 6, *supra*.

had enormous incentives to avoid competition from the Generic Competitors by entering into reverse-payment agreements.

155. Forest's willingness to provide large payments to each Generic Competitor in exchange for a multi-year delay in competition amounted to an agreement to share with the Generic Competitors the monopoly profits from sales of branded Bystolic at supracompetitive levels.

VII. ANTICOMPETITIVE EFFECT

156. The reverse-payments enabled Defendants to: (a) prevent and delay until September 17, 2021 the entry of less-expensive generic versions of Bystolic in the United States; (b) fix, raise, maintain, or stabilize the price of Bystolic products; and (c) allocate to themselves 100% of the U.S. market for Bystolic and its generic equivalents until September 17, 2021.

157. But for the unlawful reverse-payment agreements, the Generic Competitors would have begun selling a less expensive generic version of Bystolic much earlier than September 17, 2021. Such sales would have occurred via market entry by any of the Generic Competitors upon a Generic Competitor litigation victory, at risk (that is, while the patent litigation remained pending), or via a licensed entry in a settlement with Forest that did not include a side-deal or any other unlawful reverse-payments from Forest to any Generic Competitor.

158. An increasingly competitive market for Bystolic and its generic equivalents, with lower prices, would have thereafter emerged as additional generic versions of Bystolic (including, on information and belief, an authorized generic[58] version of Bystolic) entered the market. Plaintiff would have purchased generic Bystolic had it been available.

159. Defendants' unlawful concerted action has (a) delayed and suppressed the sale of generic versions of Bystolic in the United States, (b) enabled Defendants to sell Bystolic at artificially inflated, supracompetitive prices, and (c) caused Plaintiff and the Class to pay supracompetitive prices for nebivolol HCl tablets.

[58] An authorized generic is a drug manufactured under the brand's New Drug Application and licensed or sold by the brand name manufacturer with generic trade dress.

160. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT

161. During the class period, Plaintiff and members of the Class purchased substantial amounts nebivolol HCl directly from Forest and others at supracompetitive prices. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay and did pay artificially inflated prices for their requirements for nebivolol HCl. Those prices were substantially greater than the prices that Plaintiff and members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of branded Bystolic was artificially inflated by Defendants' illegal conduct, (2) Plaintiff and Class members were deprived of the opportunity to purchase lower-priced generic versions of Bystolic instead of brand Bystolic sooner, which they would have done had they had the opportunity, and/or (3) Plaintiff and Class members would have paid lower prices for generic Bystolic than the prices they actually paid for generic Bystolic.

162. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

IX. EFFECT ON INTERSTATE COMMERCE

163. At all material times, Defendants manufactured, promoted, distributed, and/or sold substantial amounts of Bystolic in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. As a direct result of the unlawful reverse-payment agreements, the Generic Competitors refrained from selling generic versions of Bystolic when they otherwise would have done so. During the relevant time period, in connection with the purchase and sale of Bystolic, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

164. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants as alleged in this Complaint were within the flow of, and have substantially affected, interstate commerce.

X. MONOPOLY POWER AND MARKET DEFINITION

165. At all relevant times, Defendants had monopoly power over nebivolol HCl products because they had the power to maintain the price of the drug they sold as Bystolic at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Bystolic.

166. "[T]he 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level."[59] And a firm that lacks monopoly power is not "likely to pay 'large sums' to induce 'others to stay out of its market.'"[60]

167. A small but significant, non-transitory price increase for Bystolic by Defendants would not have caused a significant loss of sales to non-nebivolol HCl products.

168. Bystolic does not exhibit significant, positive cross-elasticity of demand with respect to price with any non-nebivolol HCl product. Indeed, Defendants have never lowered the price of Bystolic in response to the pricing of any non-nebivolol HCl treatments for high blood pressure. In fact, Defendants substantially increased the price of Bystolic – by more than 60% – over the last five years.

169. Because of its labeling, Bystolic is differentiated from all non-nebivolol HCl products.

170. Defendants needed to control only nebivolol HCl, and no other products, in order to maintain the price of Bystolic profitably at supracompetitive prices. No non-nebivolol HCl

[59] *Actavis*, 570 U.S. at 157 (citation omitted).

[60] *Id*.

product ever rendered Defendants unable to profitably maintain or raise their prices of Bystolic without losing substantial sales.

171. Defendants also sold Bystolic at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

172. Defendants have had, and exercised, the power to exclude and restrict competition to nebivolol HCl.

173. Defendants, at all relevant times, enjoyed high barriers to entry with respect to competition to the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

174. Plaintiff alleges that the relevant market is nebivolol HCl. During the period relevant to this case, Defendants have been able to profitably maintain the price of nebivolol HCl well above competitive levels.

175. The relevant geographic market is the United States and its territories.

176. At all relevant times, Defendants' market share in the relevant market was and remains 100%, implying a substantial amount of monopoly power.

XI. CLAIM ONE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN DEFENDANTS AND HETERO)

177. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

178. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

179. Starting on or about October, 5 2012, Forest and Hetero entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse-payments to Hetero in exchange for Hetero's agreement to delay bringing its generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-

payment agreements were to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

180. The Hetero reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

181. The Hetero reverse-payment agreements harmed Plaintiff and the Class as set forth above.

182. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse-payments from Forest to Hetero that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

183. As a direct, proximate, foreseeable, and intended result of the Hetero reverse-payment-agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse-payment, Hetero would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Hetero would have agreed upon earlier entry dates untainted by delay associated with the unlawful Hetero side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Hetero and Forest would also have applied to all earlier-settling Generic Competitors, if any.

XII. CLAIM TWO
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN DEFENDANTS AND TORRENT)

184. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

185. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

186. Starting on or about November 21, 2012, Forest and Torrent entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse-payments to Hetero in exchange for Torrent's agreement to delay bringing its generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements was to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

187. The Torrent reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

188. The Torrent reverse-payment agreements harmed Plaintiff and the Class as set forth above.

189. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse-payments from Forest to Torrent that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

190. As a direct, proximate, foreseeable, and intended result of the Torrent reverse-payment-agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse-payment, Torrent would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Torrent would have agreed upon earlier entry dates untainted by delay associated with the unlawful Torrent side-deal and other reverse-payments. In addition, by

operation of the CLPs, any earlier license date agreed to between Torrent and Forest would also have applied to all earlier-settling Generic Competitors.

XIII. CLAIM THREE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN DEFENDANTS AND ALKEM)

191. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

192. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

193. Starting on or about November 27, 2012, Forest and Alkem entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse-payments to Alkem in exchange for Alkem's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements was to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

194. The Alkem reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

195. The Alkem reverse-payment agreements harmed Plaintiff and the Class as set forth above.

196. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse-payments from Forest to Alkem that outweighs their harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

197. As a direct, proximate, foreseeable, and intended result of the Alkem reverse-payment-agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse-payment, Alkem would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Alkem would have agreed upon earlier entry dates untainted by delay associated with the unlawful Alkem side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Alkem and Forest would also have applied to all earlier-settling Generic Competitors.

XIV. CLAIM FOUR
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN DEFENDANTS AND INDCHEMIE)

198. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

199. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

200. Starting on or about November 27, 2012, Forest and Indchemie entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse-payments to Indchemie in exchange for Indchemie's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements was to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

201. The Indchemie reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

202. The Indchemie reverse-payment agreements harmed Plaintiff and the Class as set forth above.

203. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse-payments from Forest to Indchemie that outweighs its harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

204. As a direct, proximate, foreseeable, and intended result of the Indchemie reverse-payment-agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse-payment, Indchemie would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Indchemie would have agreed upon earlier entry dates untainted by delay associated with the unlawful Indchemie side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Indchemie and Forest would also have applied to all earlier-settling Generic Competitors.

XV. CLAIM FIVE
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN DEFENDANTS AND GLENMARK)

205. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

206. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

207. Starting on or about December 21, 2012, Forest and Glenmark entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make

large reverse-payments to Glenmark in exchange for Glenmark's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements was to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

208. The Glenmark reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

209. The Glenmark reverse-payment agreements harmed Plaintiff and the Class as set forth above.

210. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse-payments from Forest to Glenmark that outweighs its harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

211. As a direct, proximate, foreseeable, and intended result of the Glenmark reverse-payment-agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse-payment, Glenmark would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Glenmark would have agreed upon earlier entry dates untainted by delay associated with the unlawful Glenmark side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Glenmark and Forest would also have applied to all earlier-settling Generic Competitors.

XVI. CLAIM SIX
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN DEFENDANTS AND AMERIGEN)

212. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

213. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

214. Starting on or about July 18, 2012, Forest and Amerigen entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse-payments to Amerigen in exchange for Amerigen's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements was to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

215. The Amerigen reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

216. The Amerigen reverse-payment agreements harmed Plaintiff and the Class as set forth above.

217. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse-payments from Forest to Amerigen that outweighs its harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

218. As a direct, proximate, foreseeable, and intended result of the Amerigen reverse-payment-agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed

and suffered overcharge damages as aforesaid. Specifically, without a reverse-payment, Amerigen would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Amerigen would have agreed upon earlier entry dates untainted by delay associated with the unlawful Amerigen side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Amerigen and Forest would also have applied to all earlier-settling Generic Competitors.

XVII. CLAIM SEVEN
VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 (AGREEMENT NOT TO COMPETE WITH BRAND AND GENERIC BYSTOLIC BETWEEN DEFENDANTS AND WATSON)

219. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

220. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

221. Starting on or about November 1, 2013, Forest and Watson entered into illegal contracts, combinations and conspiracies in restraint of trade under which Forest agreed to make large reverse-payments to Watson in exchange for Watson's agreement to delay bringing generic Bystolic to the market until September 17, 2021. The purpose and effect of these reverse-payment agreements was to: (a) allocate to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delay the availability of generic Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fix and maintain, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

222. The Watson reverse-payment agreements were unlawful and the reverse-payments were large and unjustified.

223. The Watson reverse-payment agreements harmed Plaintiff and the Class as set forth above.

224. By operation of the CLPs in the other Generic Competitors' reverse-payment agreements, Watson, in negotiating an entry date with Forest, could have accelerated the launch date of generic Bystolic by insisting on an entry date earlier than September 17, 2021 untainted by a reverse-payment side-deal. Instead, Watson chose to bargain for a side-deal with the same launch date as every other Generic Competitor. Thus, the Watson reverse-payment agreements are individually responsible for all of the delay in market entry of generic versions of Bystolic, and are individually responsible for all of Plaintiff's damages.

225. The Watson reverse-payment agreements were unlawful and were large and unjustified.

226. The Watson reverse-payment agreements harmed Plaintiff and the Class as set forth above.

227. There is and was no legitimate, non-pretextual, procompetitive justification for the reverse-payments from Forest to Watson that outweighs its harmful effect. Even if there were some conceivable such justification, the payments were not necessary to achieve, nor the least restrictive means of achieving, such a purpose.

228. As a direct, proximate, foreseeable, and intended result of the Watson reverse-payment-agreements in restraint of trade, as alleged herein, Plaintiff and the Class were harmed and suffered overcharge damages as aforesaid. Specifically, without a reverse-payment, Watson would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Watson would have agreed upon earlier entry dates untainted by delay associated with the unlawful Watson side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Watson and Forest would also have applied to all earlier-settling Generic Competitors.

XVIII. CLAIM EIGHT
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN DEFENDANTS AND HETERO)

229. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

230. At all relevant times prior to September 17, 2021, Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

231. Through the Hetero reverse-payment agreements, Forest and Hetero conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

232. The Hetero reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

233. The goal, purpose and/or effect of the Hetero reverse-payment agreements was to maintain, enhance, and extend Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Hetero reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

234. Defendants and Hetero knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

235. Defendants and Hetero specifically intended that the reverse-payment agreements would maintain Defendants' monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

236. Defendants and Hetero each committed at least one overt act in furtherance of the conspiracy.

237. As a direct, proximate, foreseeable, and intended result of Defendants' and Hetero's concerted monopolistic conduct, as alleged herein, Defendants unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse-payment, Hetero would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Hetero would have agreed upon earlier entry dates untainted by delay associated with the unlawful Hetero side-deal and other reverse-payments.

XIX. CLAIM NINE
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN DEFENDANTS AND TORRENT)

238. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

239. At all relevant times prior to September 17, 2021, Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

240. Through the Torrent reverse-payment agreements, Forest and Torrent conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

241. The Torrent reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

242. The goal, purpose and/or effect of the Torrent reverse-payment agreements was to maintain, enhance, and extend Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Torrent reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

243. Defendants and Torrent knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

244. Defendants and Torrent specifically intended that the reverse-payment agreements would maintain Defendants' monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

245. Defendants and Torrent each committed at least one overt act in furtherance of the conspiracy.

246. As a direct, proximate, foreseeable, and intended result of Defendants' and Torrent's concerted monopolistic conduct, as alleged herein, Defendants unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse-payment, Torrent would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Torrent would have agreed upon earlier entry dates untainted by delay associated with the unlawful Torrent side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Torrent and Forest would also have applied to all earlier-settling Generic Competitors.

XX. CLAIM TEN
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN DEFENDANTS AND ALKEM)

247. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

248. At all relevant times prior to September 17, 2021, Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

249. Through the Alkem reverse-payment agreements, Forest and Alkem conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

250. The Alkem reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

251. The goal, purpose and/or effect of the Alkem reverse-payment agreements was to maintain, enhance, and extend Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Alkem reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

252. Defendants and Alkem knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

253. Defendants and Alkem specifically intended that the reverse-payment agreements would maintain Defendants' monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

254. Defendants and Alkem each committed at least one overt act in furtherance of the conspiracy.

255. As a direct, proximate, foreseeable, and intended result of Defendants' and Alkem's concerted monopolistic conduct, as alleged herein, Defendants unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and

suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse-payment, Alkem would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Alkem would have agreed upon earlier entry dates untainted by delay associated with the unlawful Alkem side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Alkem and Forest would also have applied to all earlier-settling Generic Competitors.

XXI. CLAIM ELEVEN
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN DEFENDANTS AND INDCHEMIE)

256. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

257. At all relevant times prior to September 17, 2021, Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

258. Through the Indchemie reverse-payment agreements, Forest and Indchemie conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

259. The Indchemie reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

260. The goal, purpose and/or effect of the Indchemie reverse-payment agreements was to maintain, enhance, and extend Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Indchemie reverse-payment agreements were intended to

and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

261. Defendants and Indchemie knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

262. Defendants and Indchemie specifically intended that the reverse-payment agreements would maintain Defendants' monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

263. Defendants and Indchemie each committed at least one overt act in furtherance of the conspiracy.

264. As a direct, proximate, foreseeable, and intended result of Defendants' and Indchemie's concerted monopolistic conduct, as alleged herein, Defendants unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse-payment, Indchemie would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Indchemie would have agreed upon earlier entry dates untainted by delay associated with the unlawful Indchemie side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Indchemie and Forest would also have applied to all earlier-settling Generic Competitors.

XXII. CLAIM TWELVE
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN DEFENDANTS AND GLENMARK)

265. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

266. At all relevant times prior to September 17, 2021, Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market.

Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

267. Through the Glenmark reverse-payment agreements, Forest and Glenmark conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

268. The Glenmark reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

269. The goal, purpose and/or effect of the Glenmark reverse-payment agreements was to maintain, enhance, and extend Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Glenmark reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

270. Defendants and Glenmark knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

271. Defendants and Glenmark specifically intended that the reverse-payment agreements would maintain Defendants' monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

272. Defendants and Glenmark each committed at least one overt act in furtherance of the conspiracy.

273. As a direct, proximate, foreseeable, and intended result of Defendants' and Glenmark concerted monopolistic conduct, as alleged herein, Defendants unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse-payment, Glenmark would have launched its generic version of Bystolic upon receiving final

FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Glenmark would have agreed upon earlier entry dates untainted by delay associated with the unlawful Glenmark side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Glenmark and Forest would also have applied to all earlier-settling Generic Competitors.

XXIII. CLAIM THIRTEEN
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN DEFENDANTS AND AMERIGEN)

274. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

275. At all relevant times prior to September 17, 2021, Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

276. Through the Amerigen reverse-payment agreements, Forest and Amerigen conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

277. The Amerigen reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

278. The goal, purpose and/or effect of the Amerigen reverse-payment agreements was to maintain, enhance, and extend Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Amerigen reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

279. Defendants and Amerigen knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

280. Defendants and Amerigen specifically intended that the reverse-payment agreements would maintain Defendants' monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

281. Defendants and Amerigen each committed at least one overt act in furtherance of the conspiracy.

282. As a direct, proximate, foreseeable, and intended result of Defendants' and Amerigen's concerted monopolistic conduct, as alleged herein, Defendants unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse-payment, Amerigen would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Amerigen would have agreed upon earlier entry dates untainted by delay associated with the unlawful Amerigen side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Amerigen and Forest would also have applied to all earlier-settling Generic Competitors.

XXIV. CLAIM FOURTEEN
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (CONSPIRACY TO MONOPOLIZE AS TO BRAND AND GENERIC BYSTOLIC – AGREEMENTS BETWEEN DEFENDANTS AND WATSON)

283. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

284. At all relevant times prior to September 17, 2021, Defendants possessed and will continue to possess substantial market power (*i.e.*, monopoly power) in the relevant market. Defendants possessed and will continue to possess the power to control and maintain prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

285. Through the Watson reverse-payment agreements, Forest and Watson conspired to unlawfully maintain Defendants' monopoly power in the relevant market by agreeing to block and delay market entry of generic versions of Bystolic.

286. The Watson reverse-payment agreements (a) allocated to Forest 100% of the U.S. sales of nebivolol HCl until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (d) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

287. The goal, purpose and/or effect of the Watson reverse-payment agreements was to maintain, enhance, and extend Defendants' monopoly power, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Watson reverse-payment agreements were intended to and did prevent and/or delay generic competition to Bystolic and enabled Defendants to continue charging supracompetitive prices for Bystolic without a substantial loss of sales.

288. Defendants and Watson knowingly and intentionally conspired to maintain, enhance, and extend Defendants' monopoly power in the relevant market.

289. Defendants and Watson specifically intended that the reverse-payment agreements would maintain Defendants' monopoly power in the relevant market, and injure Plaintiff and the Class thereby.

290. Defendants and Watson each committed at least one overt act in furtherance of the conspiracy.

291. As a direct, proximate, foreseeable, and intended result of Defendants' and Watson's concerted monopolistic conduct, as alleged herein, Defendants unlawfully maintained, enhanced, and extended its monopoly power and Plaintiff and the Class were harmed and suffered overcharge damages as a result, as alleged herein. Specifically, without a reverse-payment, Watson would have launched its generic version of Bystolic upon receiving final FDA approval, or via a lawful, separate, and independent settlement agreement whereby reasonable parties in the position of Forest and Watson would have agreed upon earlier entry dates untainted

by delay associated with the unlawful Watson side-deal and other reverse-payments. In addition, by operation of the CLPs, any earlier license date agreed to between Watson and Forest would also have applied to all earlier-settling Generic Competitors.

XXV. CLAIM FIFTEEN
VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 (MONOPOLIZATION AND MONOPOLISTIC SCHEME – FOREST/ALLERGAN/ABBVIE)

292. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

293. At all relevant times prior to September 17, 2021, Defendants possessed substantial market power (i.e., monopoly power) in the relevant market. Defendants possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

294. By entering into the reverse-payment agreements with the Generic Competitors, Defendants willfully and intentionally maintained, enhanced, and extended their monopoly power using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiffs and the Class thereby. Specifically, Defendants (a) allocated to themselves 100% of the market for nebivolol HCl in all strengths in the United States until September 17, 2021; (b) delayed the availability of generic versions of Bystolic in the United States, thereby protecting Bystolic from any generic competition until September 17, 2021; and (c) fixed and maintained, at supracompetitive levels, the price Plaintiff and Class members paid for nebivolol HCl.

295. It was Defendants' conscious object to further their dominance in the relevant market by and through the anticompetitive conduct alleged herein.

296. Defendants' anticompetitive conduct harmed competition as alleged herein.

297. As a direct, proximate, foreseeable, and intended result of their illegal and monopolistic conduct, Defendants unlawfully maintained, enhanced, and extended their monopoly power, and Plaintiff and the Class were harmed as a result, as alleged herein.

298. All of Forest's corporate successors adopted Defendants' monopolistic scheme and took actions in furtherance thereof.

XXVI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Class, pray for judgment against all Defendants, jointly and severally, as follows:

1. That the Court determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare the Plaintiff as the representative of the Class;

2. That the Court enter joint and several judgments against each of the Defendants and in favor of Plaintiff and the proposed Class for the Defendants' violations of Sections 1 and 2 of the Sherman Antitrust Act;

3. That Plaintiff and all others similarly situated be awarded damages, in an amount to be determined at trial, including post-judgment interest, suffered by reason of Defendants' violations and that those damages be trebled in accordance with the law; and

4. That Plaintiff and the proposed Class be awarded reasonable attorneys' fees and costs as provided by law; and

5. Such other and further relief as the Court may deem just and proper.

XXVII. JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all claims and complaints in this Complaint so triable.

DATED: July 23, 2020

Respectfully submitted,

J M SMITH CORPORATION d/b/a/
SMITH DRUG COMPANY

By: */s/ Bruce E. Gerstein*

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